

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 13 MAR 2006

PC/MIPO

PCT

To:
MICHAEL S. TUSCAN
MORGAN, LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE, NW.
WASHINGTON, DC 20004

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

08 MAR 2006

Applicant's or agent's file reference

FOR FURTHER ACTION

See paragraph 2 below

44921-5133WO

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/39593

24 November 2004 (24.11.2004)

24 November 2003 (24.11.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): G06F 19/00 and US Cl.: 702/19

Applicant

GENE LOGIC, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703) 305-3230

Date of completion of this opinion
13 February 2006 (13.02.2006)

Authorized officer

Carolyn Smith

Telephone No. 571-272-1600

Form PCT/ISA/237 (cover sheet) (April 2005)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/39593

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in electronic form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
See the lack of unity section of the International Search Report (Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-27

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>NONE</u> | YES |
| | Claims <u>1-27</u> | NO |
| Inventive step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-27</u> | NO |
| Industrial applicability (IA) | Claims <u>1-27</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and explanations:

Claims 1-27 lack novelty and inventive step under PCT Article 33(2)-33(3) as being anticipated by Lindemann et al. (US 2003/0124552 A1). Lindemann et al. (US 2003/0124552 A1) disclose predicting at least one toxic effect of a test agent (abstract). Lindemann et al. disclose converting hybridization data from at least one gene to a gene expression measure (0013 and 0024). Lindemann et al. disclose scoring the gene expression measure and sample prediction score (abstract, claim 13, 0310). Lindemann et al. disclose comparing sample versus control (reference) to predict toxic effect (abstract and 0144), as stated in instant claims 1 and 14. Lindemann et al. disclose exposing cell or tissue to a test agent (0008, 0268), as stated in instant claim 2. Lindemann et al. disclose normalizing data (0133-0135), as stated in instant claim 3. Lindemann et al. disclose fold-change values and log scale linear additive model (0057, 0170, 0176, 0164-0166, 0310), as stated in instant claims 4-6. Lindemann et al. disclose using quality control (0033), as stated in instant claim 7. Lindemann et al. disclose dimensional reduction by subtracting mismatches (0166), as stated in instant claim 8. Lindemann et al. disclose weighted index scores (0045, 0166), as stated in instant claim 9. Lindemann et al. disclose generating a prediction score for at least 100 genes (claims 7 and 13), as stated in instant claims 10-13. Lindemann et al. disclose loading data to a server via a remote connection and internet (0233), as stated in instant claims 15-16. Lindemann et al. disclose providing data in a database and using a tissue pathology model (abstract, 0008), as stated in instant claims 17-19. Lindemann et al. disclose outputting image file data involving toxicity studies with comparisons of compounds and metabolic pathway profiles as well as pathway studies (claims 1-2 and 17, abstract, 0026, 0040, 0229-0232, 0243), as stated in instant claims 20-25. Lindemann et al. disclose combining gene and protein expression profile data (0037), as stated in instant claim 26. Lindemann et al. disclose selecting one model to predict one toxic effect (abstract), as stated in instant claim 27.

Claims 1-27 meet the criteria set out in PCT Article 33(4), and thus meet the requirements of industrial applicability because the subject matter claimed can be made or used in industry.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claims 10, 18, 23, and 25 are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof:

Claim 10 recites the phrase "method of 1" which fails to specify if 1 is referring to claim 1.

Claim 18 fails to end in a period.

Claim 23 recites the phrase "method of 20" which fails to specify if 20 is referring to claim 20.

Claim 25 recites "CEL" without stating what this acronym stands for.